

Department of Labor and Industries
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Health Technology Assessment

Thermal Shrinkage for the Treatment of
Shoulder Instability and
Anterior Cruciate Ligament Laxity

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THERMAL SHRINKAGE

Thermal shrinkage, or electrothermal treatment, uses heat to address joint instability. Surgeons may conduct the procedure in isolation or may use thermal shrinkage as an adjunct to another repair surgery. The most common indications for thermal shrinkage are for the treatment of unstable shoulders and for the treatment of anterior cruciate ligament (ACL) laxity.

Thermal shrinkage is an outpatient procedure that involves placing a probe arthroscopically into a joint. Surgeons quantify tissue shrinkage by observing morphologic changes and volume reduction. The thermal heating of joint capsules, ligaments, and tendons results in temperature and time-dependent shrinkage. Modification of dense collagenous tissues generally occurs within a temperature range of 65° to 75°. (Indelli 2003) (Medvecky 2001)

Heating tissue may cause tissue shrinkage through collagen denaturation. (Anderson 2002) While the process may initially cause fibroblast necrosis, new fibroblast cells replace the affected collagen. Twelve weeks after the procedure, the collagen appears shortened and has a more laminar structure compared with pretreatment. (Hayes 2002) The body perceives this as an injury, and the tissues rebuild around the shorter collagen fibers. The theoretical result is a tighter, more stable joint. (AAOS 2000)

The Probes and FDA Status

Two categories of probes are currently marketed in the United States. One category uses laser energy while the second uses radiofrequency energy to apply heat.

Holmium: yttrium-aluminum-garnet (Ho:YAG) probes supply laser energy. Tissues absorb the laser energy and transform it into thermal energy. Control of heat application to tissues, the need for specialized training, and cost has limited the use of laser systems.

Radiofrequency (RF) probes have the ability to alter collagen without ablating it. The probes pass an alternating current from the probe tip into the tissue. Ions in the tissue follow the direction of the alternating current causing frictional heating. Monopolar probes allow the current to pass between the probe tip and a grounding pad. Some monopolar devices also provide feedback to the RF generator allowing for control and maintenance of temperature. For bipolar probes, the current passes between 2 points on the probe tip. Research has not shown differences in outcomes for monopolar versus bipolar systems. (Carter 2002) (Medvecky 2001)

Between 1998 and 2001, the Food and Drug Administration (FDA) granted 510(k) approval for several thermal systems from manufacturers such as ArthroCare Corp., Linvatec, Mitek Products, and Oratec Interventions, Inc. The probes are classified as “Electrosurgical cutting and coagulation device and accessories.” These electrosurgical or electrothermal systems may be used in orthopedic and arthroscopic procedures for resection, ablation, excision of soft tissue, hemostasis of blood vessels, and coagulation of soft tissue. (Hayes 2002)

Cost

Mitek Products' probes, including the side effect, reverse angled end effect, angled end effect, and the end effect, sell for \$199 per probe. The cost of the generator is between \$15,000 and \$20,000, and accessories range in price from \$117 to \$465.

ORATEC Interventions, Inc. has four probes, which range in price from \$299 to \$325. The generator, including the accessories, can be purchased for \$13,495 or can be loaned for a period of 2 or 3 years if the user agrees to sign a contract to purchase 120 probes over 2 years or 150 probes over 3 years. (Hayes 2002)

Other Insurers

Aetna covers thermal capsulorrhaphy for the treatment of glenohumeral joint instability in patients with recurrent, unidirectional dislocation. Patients must meet either of the two criteria:

1. Patients with laxity in an attenuated but otherwise intact shoulder capsule without presence of other pathology (e.g., Bankart lesion); or
2. Patients who need adjunctive tightening of persistent capsular laxity as part of capsulolabral repair of a Bankart lesion. (Aetna 2002)

Blue Cross of California has deemed electrothermal capsulorrhaphy for the treatment of shoulder instability as investigational/not medically necessary. This insurer also considers electrothermal treatment for laxity in the ligaments of the knee, elbow, and ankle as investigational/not medically necessary. The policy went into effect on September 19, 2002. (Blue 2002)

BlueCross BlueShield of Tennessee states in the May 1, 2003 policy that thermal shrinkage of the ACL is investigational. (BCBS 2003)

Excellus Health Plan, Inc., the BlueCross BlueShield carrier for upstate New York, considers thermal shrinkage investigational for shoulder instability as well as ACL laxity. The policy was last reviewed in December 2002. (Excellus 2002)

Medica of Wisconsin considers thermal capsulorrhaphy for glenohumeral instability as investigative. The Medical Technology Assessment Committee approved the policy in February 2002. (Medica 2002)

Wellmark, the Blue Cross Blue Shield carrier of Iowa and South Dakota, has deemed arthroscopic thermally induced capsulorrhaphy as a covered benefit for the treatment of recurrent shoulder disability. The last review of the policy occurred in January 2002. (Wellmark 2002)

Humana's PPO, HMO, and Medicare HMO members are not eligible for thermal capsular shrinkage for the treatment of shoulder and knee instability. The policy, which has a 2001 copyright, states, "...further studies are necessary to determine its safety and efficacy as compared with standard treatments such as an open Bankart repair." (Humana 2001)

THERMAL CAPSULORRHAPHY

Surgery may treat overuse injuries affecting the shoulder that fail nonoperative, rehabilitation programs. Operative treatments for instability address pathologic ligament laxity, decrease joint capsular volume, and identify other glenohumeral injuries. Traumatic injuries may require an open technique that tightens and reattaches the tissue. (AAOS 2000) One arthroscopic repair procedure uses energy to alter glenohumeral ligaments or the shoulder capsule. Researchers of thermal capsulorrhaphy have published their findings from histologic studies as well as case series studies.

Histologic Studies

- a. (Hayashi 1999) Hayashi examined the short and long term histological properties of the glenohumeral joint capsule of patients treated with the laser-assisted capsular shift procedure. Arthroscopic laser-assisted capsular shift patients provided tissue samples. Samples from the anterior inferior glenohumeral ligament of the joint capsule were collected before and after the procedure (range 0 to 38 months).

Physicians used a “painting” motion to apply the laser energy 1 to 2 mm from the synovial surface until maximum shrinkage occurred.

Two blinded investigators graded tissue on a scale from 0 to 2:

0 – necrotic, morphologically altered cells and collagen, reduced number of intact cells

1 – normal

2 – reactive, active cells and immature disorganized collagen, proliferation of cells

Study Population: The study included 53 joint capsule specimens from 42 patients with glenohumeral instability (15 multidirectional, 12 anteroinferior, 10 anterior, 3 posteroinferior, and 2 not specified in the medical record). Subjects had a mean age of 29.9 years.

Subjects were without acute major trauma, complete capsulolabral detachment, rotator cuff tears, subacromial impingement, or constitutional ligament laxity.

The study also included 3 subjects without joint capsule pathologic abnormalities in the study for comparison.

Results: Despite glenohumeral instability, joint capsules before the procedure did not show histologic lesions or inflammation. Laser treatment caused collagen hyalinization and cell necrosis. Samples taken between 3 and 6 months demonstrated fibrous connective tissue with reactive cells and vasculature. No inflammatory cells were prominent between 3 and 6 months after surgery. Tissues harvested at 5 and 6 months after the procedure exhibited less active fibroblasts and vascularity and showed tissue maturation. While collagen and cell morphology returned to normal at 7 to 38 months, fibroblast numbers remained elevated. Six patients experienced stiffness after the

procedure. Samples from their joint capsules showed synovial, cellular, and vascular reaction at 1 year.

Conclusion: This study revealed histologic evidence of tissue healing over time after a laser-assisted capsular shift procedure. Cellular damage and collagen denaturation occurred immediately after laser application. Joint capsule tissue showed vascularized cellular connective tissue at 3 months and gradual maturation at 7 months. No permanent tissue injury or severe inflammation occurred.

- b. (McFarland 2002) McFarland compared tissue samples from patients who failed capsular shift operations to tissue samples from patients who failed thermal capsulorrhaphy. Samples from cadavers acted as control tissue. Researchers sampled the middle glenohumeral ligament, and an unblinded pathologist examined the tissue.

Study population: The study included samples from 12 patients who underwent an open stabilization procedure, 7 patients who failed thermal capsulorrhaphy, and 6 fresh-frozen cadaveric shoulders. Five of the thermal shrinkage patients were diagnosed with anterior instability, and two were diagnosed with anterior instability with hyperlaxity. Six of the procedures used RF probes to provide energy.

Results: The histologic appearance of the failed thermal group differed from the normal samples, but were similar to the dislocator group. The failed thermal capsulorrhaphy group had significantly more samples with denuded synovium and hyalinized collagen than the dislocator group.

Histologic Findings	Normal (n=6)	Dislocator (n=12)	Failed Thermal (n=7)
Synovial layer			
Normal	6 (100%)	3 (25%)	0 (0%)
Denuded	0 (0%)	7 (58%)	7 (100%)
Hypertrophic	0 (0%)	2 (17%)	0 (0%)
Collagen layer			
Collagen			
Normal	6 (100%)	6 (50%)	0 (0%)
Fibrotic	0 (0%)	5 (42%)	2 (29%)
Hyalinization	0 (0%)	1 (8%)	5 (71%)
Cellularity			
Normal	6 (100%)	9 (75%)	5 (71%)
Increased	0 (0%)	3 (25%)	2 (29%)

Conclusion: No one histologic observation explained the attenuation of the capsule in failed thermal treatment.

Retrospective Case Series

- a. (Hovis 2002) The retrospective review reports on posterior glenohumeral instability associated with subacromial impingement among elite golfers.

Physicians conducted the procedure with a laser for one patient and a RF probe for the other patients. Three patients with positive impingement signs and pain relief from the impingement test underwent arthroscopic subacromial decompression. One of these patients also underwent arthroscopic distal clavicle excision for acromioclavicular joint arthrosis.

Shoulders were immobilized for 2 to 3 weeks until beginning a motion therapy program at 4 weeks and strengthening exercises at 6 to 8 weeks.

Study Population: The study included 8 golfers who presented with posterior instability. The six patients who underwent surgery demonstrated unilateral, unidirectional instability. Each had increased posterior translation of grade II or III in the shoulder compared to the uninvolved shoulder. The mean age at diagnosis was 35 years (range 16 to 47 years).

Results: Two patients improved with nonoperative treatment and returned to play immediately. Six patients underwent shoulder arthroscopy with posterior thermal capsulorrhaphy. Four of the 6 also underwent arthroscopic subacromial decompression. The 6 surgically treated patients returned to play at an average 4 months after surgery. At an average 4.5 years of follow-up, all 8 patients were playing at their previous level of competitive play.

Conclusion: This study increases awareness of the diagnosis of posterior instability of the shoulder in elite golfers. Posterior thermal capsulorrhaphy was successful in treating the posterior instability.

- b. (Lephart 2002) Because monopolar RF energy may denature collagen during thermal capsulorrhaphy, Lephart hypothesized that thermal treatment would adversely effect the mechanoreceptors in the capsule. To test the hypothesis, a retrospective case series to evaluate proprioception function and functional deficits following monopolar RF thermal capsulorrhaphy.

Subjects were bilaterally tested retrospectively 6 to 24 months (mean 11.90 months) following surgery. An electromagnetic motion analysis system measured each subject's ability to reproduce joint positions (ARJP) and reproduce paths of motion (PMR). A proprioception testing device measured passive reproduction of joint positions (PRJP) and threshold to detect passive motion (TTDPM). The Shoulder Rating Questionnaire (SRQ) measured function.

Study Population: The study included 20 subjects with an average age of 21.4 years. All subjects received diagnoses of unilateral anterior, anteroinferior, or multidirectional glenohumeral instability with no significant concomitant pathologies. Capsular redundancy was the primary diagnosis in all subjects.

Results: Statistical analysis revealed a significant ARJP difference between the involved and uninvolved limb indicating less reproduction error with the involved limb compared to the uninvolved limb. No significant interactions were present for TTDPM, PRJP, or PMR. The SRQ score of 91.86 indicates that the subjects returned to near normal

function at the time of testing.

Average Patient Score	
Assessment Category	Points
Pain (40 points)	37.00
Activities of daily living (20 points)	19.23
Occupational ability (10 points)	9.85
Athletic-recreational (15 points)	12.80

Conclusions: No appreciative effects exist with proprioception and function following treatment of shoulder instability with thermal capsulorrhaphy. Three mechanisms may account for the normalized proprioception: effects of postoperative rehabilitation, healing effect of thermally treated tissue, and reestablishment of capsular tension.

- c. (Levitz 2001) Levitz reported return to sport following arthroscopic treatment of internal impingement with and without thermal capsulorrhaphy in throwing athletes.

The first phase of the study involved a retrospective chart review of baseball players who underwent arthroscopy for labral and rotator cuff pathology. Patients with a history of surgery were excluded from the study.

Subjects in the nonheat-probe group (NHP) presented with pain during the cocking phase of the throwing motion. External rotation greater than 100°, 50% anterior translation, and a positive drive-through sign defined glenohumeral (GH) laxity. Patients failing to respond to physical therapy and patients with labral tears or partial rotator cuff tears underwent debridement. SLAP lesions were repaired with suture anchors placed on the glenoid rim followed by passage of one limb of the suture through the labral tissue.

Phase II of the study consisted of retrospectively identifying the heat-probe (HP) group. Cases involved baseball players who underwent monopolar electrothermal capsular shrinkage concomitantly to rotator cuff and labral repair. The technique of thermal capsulorrhaphy consisted of painting the shoulder capsule through the anterior portal.

Study Population: Of the 52 baseball players identified in Phase I, 1 player was excluded for not meeting the criteria for laxity. As a result, the NHP group included 51 subjects with GH laxity and internal impingement.

Phase II identified 31 subjects with a mean age of 24 years for the HP group. The HP rehabilitation program also included use of a sling for an additional 2 weeks and stretching exercises conducted at a slower pace.

Number of Subjects by Procedure

	NHP	HP
Labral Debridement	7	4
Rotator Cuff Debridement	1	6
Labral and Cuff Debridement	29	8
Labral Repair and Cuff Debridement	13	13
Rotator Cuff/Labral Debridement/Acromioplasty	1	0

Results: In the NHP group, 41 of 51 throwers (80%) returned to competition after an average of 7.2 months. At 30-month follow-up, 34 (67%) were still competing, and 31 (61%) were at preinjury levels of competition.

In the HP group, 31 throwers had a 30-month follow-up. Of the 31 subjects, 30 (97%) returned to competition at a mean of 8.4 months. At 30 months, 28 (90%) subjects were still competing, and 27 (87%) were competing at preinjury levels of competition.

At 18 months after surgery, thermal capsulorrhaphy did not have a significant effect in athletes with labral detachment. After 2 years, there was no significant difference between those patients who required labral repair and those patients who underwent only a labral or rotator cuff debridement.

Number And Percent of Subjects who Returned to Activity

	HP group	NHP group
Available for follow-up	31	51
Return to play	30 (97%)	41 (80%)
Still competing at 30 months	28 (90%)	34 (67%)
Competing at preinjury levels	27 (87%)	31 (61%)

Conclusions: Monopolar RF electrothermal capsulorrhaphy appears to improve the results of arthroscopic treatment of internal impingement, provided the primary pathology is addressed.

- d. (Lyons 2001) Lyons conducted a retrospective case series of laser-assisted capsulorrhaphy for multidirectional shoulder instability (MDI) with minimum follow-up of 2 years.

The holmium:YAG laser provided an energy level of 10 W (1 J per pulse at a rate of 10 Hz) and operated at a wavelength of 2.1 μm . For anterior or inferior capsulorrhaphy, the laser entered through the anterior portal and proceeded laterally from the glenoid. If the interval capsule failed to respond to laser treatment, plication sutures were placed.

Assessment outcomes included incidence of instability, reoperation, and return to previous level of activity or sports. In addition, the researchers rated patients as satisfactory or unsatisfactory using Neer criteria¹.

Study Population: Case review identified 32 patients who underwent laser-assisted capsulorrhaphy for MDI. Six patients with anterior or posterior labral or capsular tears requiring repair were excluded. As a result, the study included 27 shoulders in 26 patients who had a mean age of 25 years (range 16 to 46 years).

¹Neer classification

Satisfactory	Unsatisfactory
No recurrence of dislocation or subluxation	Failure to meet the criteria for satisfactory
No pain	
Full activities	
Normal strength	
Within 10° of full extension and 40° of rotation compared with contralateral shoulder	

The dominant extremity was involved in 20 patients. All patients underwent nonoperative treatment including physical therapy for the rotator cuff, scapular stabilizer strengthening, and activities modification for at least 3 months. The time from the initial complaint of pain or instability to surgery averaged 21 months (range 3 months to 11 years).

Patients who had undergone previous surgery on the shoulder were excluded from the study. In addition, patients with a Bankart lesion or any labral tear that required stabilization were not included in the study.

Results: All patients were available for follow-up, which averaged 27 months (range 24 to 35 months). Two years after surgery, 26 of 27 shoulders (96%) remained stable and asymptomatic. Of 14 athletes in the study group, 12 (86%) returned to their previous level of sports participation.

Three patients (12%) had an unsatisfactory rating using the Neer criteria.

Conclusion: Laser-assisted capsulorrhaphy effectively treats patients with MDI.

Prospective Case Series

- a. (Fitzgerald 2002) The prospective case series described the results of thermal capsulorrhaphy in the treatment of multidirectional shoulder instability (MDI). Surgeons applied heat to the capsule and entire ligament complex by using the painting method.

Researchers evaluated patients with the 35-point UCLA shoulder rating score, which assessed pain, functional level, amount of forward flexion, strength of forward flexion, and patient satisfaction. Follow-up occurred at 12-month intervals postoperatively. Researchers defined a score of 34 points or greater as excellent, 29 to 33 points as good, and less than 29 points as poor.

Study Population: The study included 33 consecutive patients with MDI treated with arthroscopic thermal capsulorrhaphy. Of the 33 study subjects, 30 (90%) were on active military duty. Patient age averaged 27 years (range 17 to 41 years). Twelve patients had a history of traumatic dislocation, and 20 patients (66%) experienced recurrent painful subluxations. Three patients had been previously treated with open inferior capsular shift procedures.

Eleven patients (33%) demonstrated both anterior and posterior instability. Load and shift testing showed that 14 (42%) had primarily anterior and inferior instability, and 8 (25%) demonstrated posterior and inferior instability. Bilateral elbow hyperextensibility and the ability of the abducted thumb to reach the ipsilateral forearm showed generalized ligamentous laxity (GLL) in 24 patients (73%).

Subjects had a history of instability in more than one direction, 6 months of physical therapy, translation over the glenoid rim, a positive sulcus sign with inferior stress, and

increased capsular volume as shown in diagnostic arthroscopy. The study excluded voluntary dislocators.

Results: Thirty patients were available at a mean follow-up of 36 months (range 24 to 40 months).

Twenty-three (76%) subjects gave satisfactory ratings and were able to return to activity and previous occupation, including 21 active-duty subjects. Patients returned to activity when the operated shoulder and the contralateral shoulder had equal range of motion and strength. Return to activity occurred after an average of 4.7 months.

According to the UCLA score, 3 shoulders (10%) received excellent ratings; 20 (67%) were rated as good, including 2 patients who failed open capsular shifts; and 7 (23%) were rated as poor, including a patient who failed open capsular shift.

Of the 7 patients who received poor UCLA ratings, 4 complained of persistent pain, and 3 suffered recurrent subluxation. Seven active-duty patients received discharges for not returning to mandatory levels of activity.

Mean UCLA scale scores increased from 16.7 preoperatively to 28.7 points at 12 months and 30.1 points at final follow-up. While the difference in preoperative and final UCLA scores was statistically significant, the difference in the 12-month and final UCLA scores was not significant.

Conclusion: The researchers conclude, "While the procedure has a low associated morbidity, it is too early to ascertain its specific beneficial role in the treatment of MDI or to determine whether the results will degrade."

- b. (Levy 2000) Levy presents results from a prospective case series study of laser and RF thermal shrinkage for patients with multidirectional or capsular stretch-type instability.

Use of the holmium:YAG laser at low power produced non-ablative capsule shrinking. Average energy settings were 12 W (range 4 to 19 W) for the power setting, 1.13 J (range 0.5 to 1.6 J) for the energy setting, and 3.1 kJ (range 0.5 to 6.2 kJ) for the total energy. The energy settings for the monopolar RF generator were 40 W, 67°C. The bipolar system was set in the 14 to 20 W range. Tissue response controlled thermal energy application.

Researchers evaluated Constant and Walch-Duplay scores with regard to pain, stability, mobility and return to sport or daily activities, and patients' impression. Follow-up occurred at 3 weeks, at 3, 6, 9, 12, 18 and 24 months, and yearly thereafter.

Study Population: Researchers used laser-assisted capsular shrinkage (LACS) to treat 56 patients (61 shoulders) and RF capsular shrinkage to treat 34 patients (38 shoulders).

The study included subjects based on the following criteria:

- 1) pain or instability despite 3 to 6 months of conservative management, which included rotator cuff strengthening and activity modification.

- 2) a history of repetitive microtrauma or a minimal traumatic event leading to recurrent symptoms of instability (pain, subluxation or true dislocation);
- 3) generalized laxity in association with signs of multidirectional or unidirectional instability
- 4) arthroscopic findings of a capsule with increased joint volume without a Bankart or Hill-Sachs bony lesion.

Number of Subjects by Diagnosis

	LACS	RF
true multidirectional instability	30	22
multidirectional laxity	31	16
anteroinferior instability	20	14
posteroinferior instability	9	2
anterior instability	1	0
posterior instability	1	0

Exclusion criteria included unidirectional instability with a history of significant trauma or a Hill-Sachs or Bankart lesion observed during arthroscopy. In the group undergoing LACS, researchers did not exclude 9 patients who had previously undergone open stabilization. However, patients who had more than one open shoulder stabilization procedure were excluded from the RF group.

The patients treated with the holmium:YAG laser had a mean age of 26 years (range 15 to 52 years) and mean follow-up of 40.5 months (range 31 to 57 months). The patients treated with RF had a mean age of 23.9 years (range 14 to 53 years) and mean follow-up of 23 months (range 14 to 33 months).

Results: Eighteen months after the operation, the LACS group mean Walch-Duplay score improved to 90 points, but then declined to approximately 80 points at 36 months.

Despite a failure rate of 36.1% in the LACS group, 59% of patients considered their shoulders improved. Of the 15 (24.5%) subjects who experienced redislocation, 8 resulted from traumatic accidents between 6 and 14 months after surgery. Seven patients redislocated after minimal trauma between 3 and 24 months after surgery. In addition, 7 LACS patients had recurrent subluxations and/or symptoms of instability.

The RF group averaged 80 points on the Walch-Duplay and Constant scores at follow-up, and 76.3% of patients considered their shoulder improved. RF failed in 9 shoulders (23.7%) due to traumatic dislocation in 2 patients and atraumatic dislocations, subluxations, or pain in 7 subjects.

Of the 6 patients who underwent repeat RF procedures, 4 had a second treatment 5 to 10 months after the first procedure. Two LACS subjects had RF treatment 18 months and 2 years, respectively, after LACS. One patient had a second LACS procedure 18 months after the first LACS procedure. Three patients had open stabilizations 6 to 10 months after the last thermal treatment.

Conclusion: The authors conclude that the outcome score of 80 points, minimal morbidity, and lack of complications make this procedure a viable alternative to open capsular shift in this difficult group of patients.

- c. (Mishra 2001) Mishra studied the effect of arthroscopic labral repair with monopolar RF thermal shrinkage for the treatment of labral detachment and capsular redundancy in shoulders with recurrent instability.

The prospective study used the Rowe score to assess pain, range of motion, stability, and function at minimum 2-year follow-up. Researchers compared median preoperative to mean postoperative scores.

Study Population: The study included 42 patients who sustained at least 2 complete anterior dislocations and had capsulolabral avulsions. The group had a mean age of 27 years (range 15 to 44 years) and had experienced an average of 9 dislocations. The time between initial dislocation to surgery averaged 69 months (range 3 to 288 months).

Subjects were excluded due to posterior instability, multidirectional instability, capsular laxity without Bankart lesion, shoulders with humeral avulsion of the glenohumeral ligaments, rotator cuff tears, SLAP lesions, irreparable capsule defects, and previous shoulder stabilization.

Results: The average follow-up from surgery to final evaluation was 28 months (range 24 to 48 months). Thirty-eight subjects returned to sport activity, and 31 patients had full shoulder motion. Three patients had postoperative dislocations.

Modified Rowe Score

	Preoperative	Postoperative
Pain	7.1	9.5
Stability	0.4	26.0
Motion	7.4	8.7
Function	21.1	45.0
Overall	37.8	89.1

Conclusion: The results indicate that arthroscopic treatment for recurrent traumatic anterior instability yields results comparable to open procedures.

- d. (Savoie 2000) Savoie compares the results of laser-assisted capsulorrhaphy, arthroscopic capsular shift, and thermal capsular tightening with rotator interval plication. The UCLA, Rowe rating, and Neer-Foster scales measured patient abilities. Measurements were taken at 1 week, 3 weeks, and each month after surgery until the patient was released. Follow-up occurred at average 26 months (range 20 to 27 months).

Study Population: The study included 30 patients treated with monopolar RF capsular shrinkage. The patients had an average age of 22 years (range 16 to 32 years). All patients underwent for at least 6 months conservative therapy and activity modification. Thirty months elapsed between initial complaint and surgery.

Twenty RF patients were involved in sports activities. A single traumatic event caused shoulder instability for 3 patients. Generalized laxity was detected in 27 of 30 patients (91%). All patients had suture plications to treat rotator interval laxity.

One comparison group consisted of 26 MDI patients treated with arthroscopic capsular shifts with an average age of 26 years (range 15 to 39 years). This group had an average follow-up of 52 months (range 28 to 72 months). Thirteen patients had confirmed dislocations, and all subjects had subluxations that failed conservative therapy.

A second comparison group consisted of 32 patients with a mean age of 25 years (range 16 to 46 years) treated with laser capsular shrinkage. Follow-up for the laser group averaged 27 months (range 24 to 35 months).

Results: Of the 30 RF subjects, 28 received satisfactory ratings.

Of the 32 laser subjects at average 27-month follow-up, one patient developed post-operative instability, and one patient sustained a rotator cuff injury.

Three patients in the suture group experienced recurrent instability.

Conclusion: The researchers find that the results of thermal capsulorrhaphy are similar to results after laser and open procedures in the areas of instability incidence, need for reoperation, and return to sport ability.

Risk Factors for Failure

(Anderson 2002) Anderson studied the risk factors for poor outcome after monopolar RF thermal capsulorrhaphy. Out of 106 patients, the researchers retrospectively identified 15 patients who failed thermal capsulorrhaphy. The average follow-up for the study population was 13 months (range 5 to 29 months). Redislocation, reoperation, or a L'Insalata shoulder score of less than 70 points defined treatment failure.

Study Population: The mean age of the 106 patients was 26 years (range 15 to 52 years). An average of 6.3 months (range 1 to 16 months) elapsed before treatment failure.

The study population included patients who underwent an isolated thermal capsulorrhaphy as well as patients who had thermal treatment as an adjunct to another procedure. Patients treated with bipolar RF or laser thermal energy were excluded.

Results: The study found a significant association between poor outcome and previous operation as well as multiple recurrent dislocations. Multidirectional instability and participation in contact sports did not attain statistical significance as risk factors. A concomitant procedure at the time of thermal capsulorrhaphy was not associated with poor outcome.

Conclusion: Thermal capsulorrhaphy may not benefit patients who have had prior operations or have a history of multiple dislocations. The data also suggest that the procedure should be used cautiously for patients who play contact sports or patients with multidirectional instability.

Adverse Events

(Greis 2001) Greis reports 4 cases of axillary nerve injury after RF capsular shrinkage of the shoulder. Sensory findings were found in 2 cases. Both sensory and motor injuries occurred in 2 other cases. The authors conclude that axillary nerve injury during thermal capsular shrinkage may result from heat penetration through the capsule to the nerve.

Treatment Alternatives

Labral repair with capsular shift for unidirectional instability averages a rate of recurrent instability of approximately 3% (range 0% to 30%). The open inferior capsular shift for multidirectional instability averages a recurrence rate of approximately 10% (range 0% to 13%). (Medvecky 2001)

Procedural Codes

Current Procedural Terminology 2003 recommends using 29999 to report arthroscopic thermal capsulorrhaphy and 23929 to report open thermal capsulorrhaphy.

Department Experience

In 2002, the Department of Labor and Industries reimbursed 106 cases of open capsulorrhaphy and 248 cases of arthroscopic capsulorrhaphy.

CPT code	Procedure Description	Number of Allowed Claims
23450	Capsulorrhaphy, anterior; Putti-Platt procedure or Magnuson type operation	14
23455	with labral repair (eg, Bankart repair)	67
23460	Capsulorrhaphy, anterior; any type; with bone block	1
23465	Capsulorrhaphy, glenohumeral joint; posterior, with or without bone block	2
23466	Capsulorrhaphy, glenohumeral joint, any type multidirectional instability	22
29806	Arthroscopy, shoulder surgical; capsulorrhaphy	54
29807	repair of SLAP lesion	157
29819	with removal of loose body or foreign body	20
29820	synovectomy, partial	17
29821	synovectomy, complete	1

THERMAL SHRINKAGE FOR THE ANTERIOR CRUCIATE LIGAMENT

Patients with ACL instability resulting from incomplete tears or elongation in continuity without ligament detachment historically undergo conservative treatment or graft replacement. (Carter 2002) Two researchers have published their findings from an alternate treatment of addressing ligament laxity with thermal energy.

Prospective Case Series

- a. (Carter 2002) Carter evaluated the efficacy of electrothermal collagen shrinkage for the treatment anterior cruciate ligament (ACL) laxity.

Evaluations included range of motion testing, the Lachman and pivot shift tests, and KT-1000 arthrometer testing. Follow-up occurred at monthly intervals until 6 months elapsed. Then, patients were requested to return at 6-month intervals.

Researchers defined success as a functionally stable knee, a negative Lachman test, arthrometer score of 3 mm or less, and a negative pivot shift test. In contrast, treatment failure was defined by 5 mm or more side-to-side difference and by functional knee instability.

Surgeons used a monopolar RF device set at 67°C and 40 W of power. Use of the probe began at the distal end of the ACL and continued proximally to its attachment on the femur. Physicians visualized tissue shortening and placed the probe within the ligament to confirm ACL tautness.

Postoperatively, patients wore a knee immobilizer for 4 weeks and attempted weightbearing as tolerated. Patients were released to full activities at 4 months if they attained full range of motion, 80% muscle strength as compared with the contralateral limb, and normal functional testing.

Study Population: Eighteen patients with laxity and ACL continuity underwent arthroscopic electrothermal shrinkage. The average patient age was 26.8 years (range 15 to 40 years).

Four patients had undergone previous reconstruction. Arthrometer testing confirmed anterior laxity. Involved knees had more than 3 mm of anterior excursion at maximum force compared with the opposite knee.

Results: Arthrometer scores at 1 month showed a decrease in anterior excursion with an average side-to-side difference of 1.9 mm.

The average follow-up in the successful group was 20.5 months (range 13 to 27 months). Of the 7 patients with successful outcomes, 6 patients received treatment in the acute phase to their native ACL. One patient had a patellar tendon graft and

received treatment in the chronic stage. Arthrometer scores at last follow-up did not differ from measurements taken at 6 months. Researchers did not detect changes between preoperative and postoperative activity levels.

Eleven patients failed treatment at an average of 4.0 months (range 2 to 8 months) and requested ACL revision surgery. Whereas all patients had a firm endpoint prior to operation, 4 subjects had a firm endpoint at last follow-up.

There was no relationship between ACL tissue type or initial degree of laxity and the time or mode (stretch versus tear) of failure.

Conclusion: The researchers state, "RF thermal shrinkage has limited application for patients with ACL laxity. The technique should not be used in treating patients with chronically lax ACL or those who have undergone previous reconstructions. Although the procedure may treat acutely injured native ACL, further study is needed to see if the ligament stretches out over time or is at increased risk of reinjury."

- b. (Indelli 2003) Indelli presents the results of monopolar RF thermal repair on 28 symptomatically unstable knees with partial ACL tears.

The study used 2 different monopolar electrothermal devices. Approximately half of the anterior ACL received thermal energy beginning from the distal end of the ligament and continuing proximally to its attachment on the femur. Rehabilitation included use of a brace for at least 6 weeks and progressive weightbearing.

A 2-year minimum follow-up (range 24 to 35 months) followed International Knee Documentation Committee guidelines.

Study Populations: The study included 28 patients with an average age of 36.5 years (range 21 to 54 years). They had symptomatic lesions that were an average of 77 days old (range 7 to 180 days). Twenty-three patients received treatment to their native ACL, whereas 5 patients received therapy to ACL reconstructions.

The study used the following inclusion criteria:

- a difference of 6 mm when comparing knees using the KT-1000 evaluation;
- ligamentous continuity, but with laxity by interstitial disruption and attenuation;
- lack of proximal, distal, or midportion ligament detachment;
- adequate vascularization of remaining tissue;
- instability for less than 6 months;
- a positive Lachman and pivot shift maneuver.

Patients were excluded due to immunologically mediated systemic disease, illnesses requiring the use of corticosteroids, and smoking.

Results: Prior to the procedure, KT-1000 evaluations showed a 9 mm (range 6 to 13 mm) average difference when comparing knees. At follow-up (range 24 to 35 months), the KT-1000 assessment showed a 1.9 mm difference and a normal or

nearly normal result in 96% of patients. The side-to-side difference in AP translation with 134 N of force was 2 mm or less in 26 patients, and 3 mm in one patient. The pivot shift test was normal in 21 (75%) and nearly normal in six (21%) patients. Full ROM was regained by 88% of the patients, and loss of flexion was less than 5° in the remaining 3 patients.

One patient failed treatment with 13 mm side-to-side difference and an abnormal pivot shift test.

Conclusion: The authors conclude that the procedure seems to be a reasonable alternative to ACL grafting in selected patients because the results compare to results following ACL reconstruction with allograft, patellar, or hamstring tissue.

Treatment Failure Case Studies

- a. (Sekiya 2000) Sekiya presents a case of a 16 year-old female patient who underwent an arthroscopic reconstruction of the ACL with a semitendinosus-gracilis graft and a partial lateral meniscectomy. The intraoperative Lachman test was negative after reconstruction. Five months later, the patient reinjured the ACL graft and tore the medial meniscus. A RF probe set at 65° C and 40 W of energy tightened the graft. Two weeks following the reinjury, a revision ACL reconstruction with a bone-patellar tendon-bone autograft and a medial meniscal repair were performed arthroscopically.

Sekiya suggests that heat shrinkage may have failed for 2 reasons. First, the amount of shrinkage required to decrease anterior-posterior translation from 10 mm to 3 mm was on the order of 40 percent, which is greater than literature recommendations. Second, complete resorption of the graft occurred. Alteration in collagen structure and heat-related necrosis may have led to immune-mediated autodigestion.

- b. (Perry 2000) Perry reports a case of spontaneous, simultaneous rupture of the anterior and posterior cruciate ligaments 3 months after RF thermal probe treatment. The patient had no previous traumatic injury to the knee. Simultaneous rupture occurred under minimal physiologic load.

Department Experience

In 2002, the Department of Labor and Industries accepted the following number of cases using diagnosis codes describing sprains and strains of ligaments in the knee and leg. Cases may have been accepted under multiple codes.

Code	Description	Number of Accepted Cases
844	Sprains and Strains of Knee and Leg	716
844.1	Medial Collateral Ligament of Knee	863
844.2	Cruciate Ligament of Knee	1023
844.3	Tibiofibular (joint) (ligament), superior	23
844.8	Other	1365
844.9	Unspecified	5152

CONCLUSION

Thermal shrinkage of tissue is an arthroscopic technique used for the treatment of shoulder instability and anterior cruciate ligament laxity. While researchers have published their findings in peer-reviewed journals, the evidence comes primarily from case series studies with small study populations. Therefore, findings do not substantially show thermal shrinkage's efficacy or effectiveness for the treatment of shoulder instability or anterior cruciate ligament laxity.

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